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21 July 2016

URGENT: FIELD SAFETY NOTICE
RECALL: Sterile RENASYS[®] Transparent Film
FIELD SAFETY NOTICE: WR-2016-03

Affected Product: Sterile RENASYS[®] Transparent Film
FSCA reference: WR-2016-03
FSCA action: Device Recall
Details of affected product: See Annex One

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Device Customer/Distributor,

Smith & Nephew informs you of a voluntary Field Safety Corrective Action (FSCA) in relation to the Sterile RENASYS[®] Transparent Film and the RENASYS[®] Dressing kits that contain the folded RENASYS[®] Transparent Film. The folded Sterile RENASYS[®] Transparent Film is used in with Gauze Dressing kits and is intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems.

Smith & Nephew have identified seal integrity failures on the folded Sterile RENASYS[®] Transparent Film pouches during transit testing. All the seal integrity failures identified during the testing occurred at the point where the Sterile RENASYS[®] Transparent Film pouches were folded during the packaging process.

Smith & Nephew have identified that the process of folding the Sterile RENASYS[®] Transparent Film pouch during its packaging has the potential to damage the pouch seals resulting in a loss of sterility of the product. The loss of sterility has the potential to contribute to a local infection.

To date Smith & Nephew is not aware of any complaints reported in relation to this issue.

The scope of this FSCA is only limited to the folded sterile RENASYS[®] Transparent Film and the RENASYS[®] Gauze kits that contain the folded sterile RENASYS[®] Transparent Film. The scope of the FSCA does not extend to the other Dressing kits and components of the RENASYS[®] NPWT Systems. Figures One, Two and Three illustrate examples of the affected items in this FSCA.

The purpose of this Field Safety Notice is to provide information to identify the affected items and to communicate the necessary actions to be undertaken by customers and distributors.



Figure One – Folded Sterile RENASYS® Transparent Film



Figure Two – The RENASYS® Transparent Film contained in the RENASYS® Gauze Dressing Kits

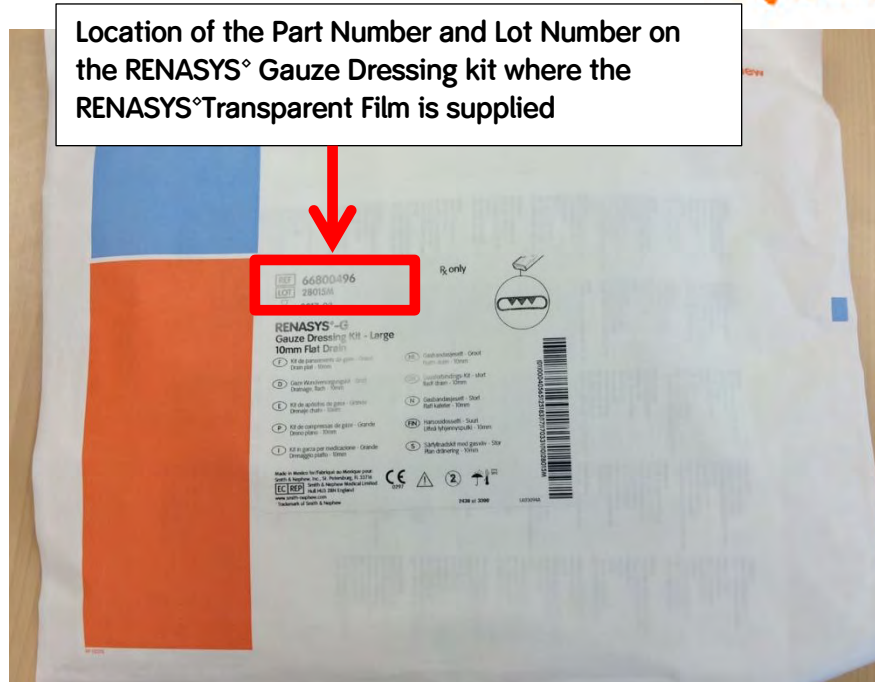


Figure Five – Location of the Part Number and Lot Number of the Gauze Dressing kits where RENASYS[®] Transparent Film is supplied.

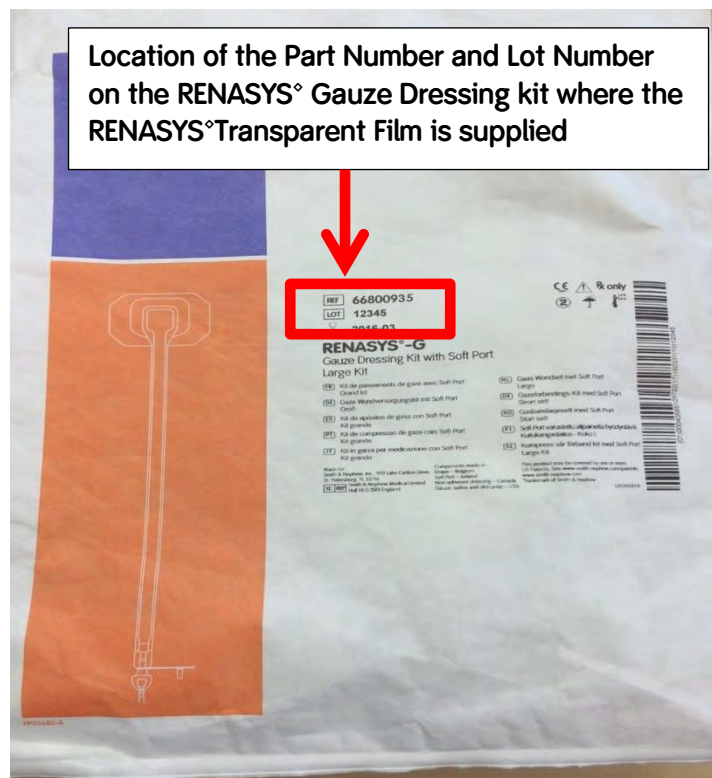


Figure Six – Location of the Part Number and Lot Number of the Gauze Dressing kits where RENASYS[®] Transparent Film is supplied.

Description of the problem:

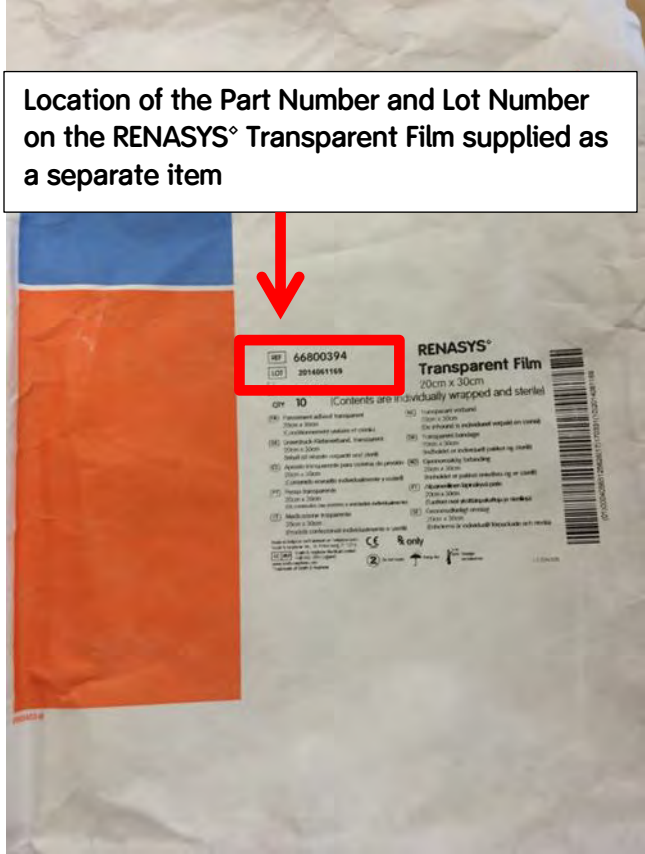
Smith & Nephew have identified seal integrity failures on a small number of folded Sterile RENASYS[®] Transparent Film pouches during transit testing. All the seal integrity failures identified during the testing occurred at the point where the Sterile RENASYS[®] Transparent Film pouches were folded during the packaging process.

Smith & Nephew have identified that the process of folding the Sterile RENASYS[®] Transparent Film pouch during its packaging has the potential to damage the pouch seals resulting in a loss of sterility of the product. the loss of sterility has the potential to contribute to a local infection.

To date Smith & Nephew is not aware of any complaints reported in relation to this issue that has led to a local infection.

Upon the identification of the root cause, Smith & Nephew have implemented appropriate corrective actions.

Actions to be taken by Customers and Distributors

No.	Actions to be undertaken
1	<p>Identify users of the affected folded Sterile RENASYS[®] Transparent Film and the RENASYS[®] Gauze Dressing kits that contains the folded Sterile RENASYS[®] Transparent Film.</p> <p>This requires you to identify all users of Smith & Nephew RENASYS[®] NPWT systems, who may be in possession of an affected items and need to be made aware of this issue and the actions to be executed in this Field Safety Corrective Action.</p> <p>Users may be distributors, healthcare professionals, home care workers or patients. Provide copies of this Field Safety Notice to all identified users as soon as is reasonably practicable.</p>
2	<p>Users are instructed to immediately inspect the Part Number and the Lot Number for the folded Sterile RENASYS[®] Transparent Film and the RENASYS[®] Gauze Dressing kits that contains the RENASYS[®] Transparent Film. Figures Seven, Eight and Nine, below, illustrate where the Part Numbers and Lot Numbers are located.</p> <div data-bbox="532 919 1172 1768" data-label="Image">  </div> <p>Figure Seven - Location of the Part Number and Lot Number of the affected RENASYS[®] Transparent Film supplied as a separate item</p>

Location of the Part Number and Lot Number on the RENASYS[®] Gauze Dressing kit where the RENASYS[®] Transparent Film is supplied

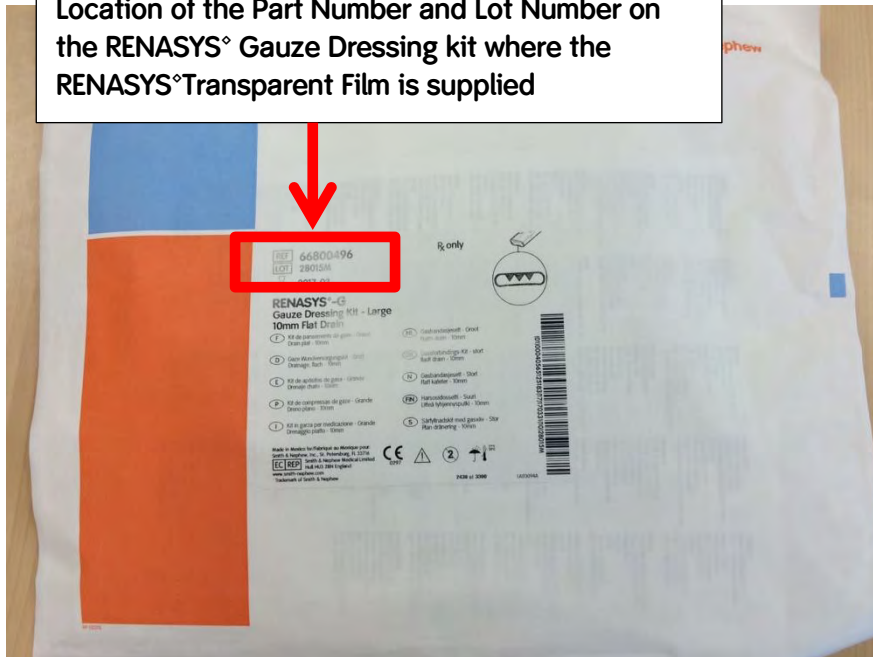


Figure Eight - Location of the Part Number and Lot Number of the Gauze Dressing kits where RENASYS[®] Transparent Film is supplied

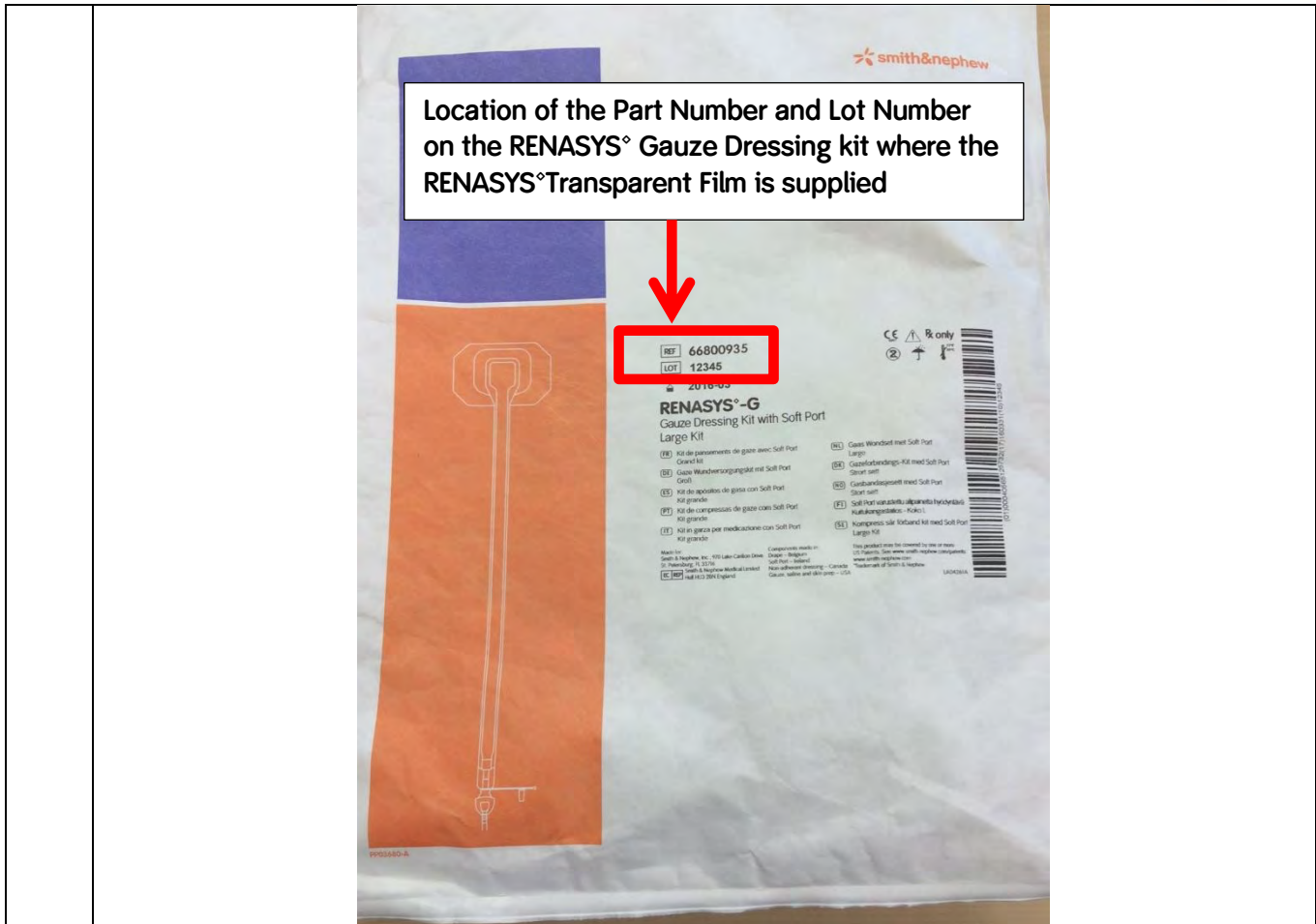


Figure Nine - Location of the Part Number and Lot Number of the Gauze Dressing kits where RENASYS[®] Transparent Film is supplied

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|----------|--|
| 3 | Users are instructed to quarantine all affected folded Sterile RENASYS[®] Transparent Film and/or the RENASYS[®] Gauze Dressing kits that contains the folded Sterile RENASYS[®] Transparent Film. |
| 4 | In the event that a Transparent Film is required for NPWT therapy, the responsible Health Care Professional should be consulted to determine an alternative Transparent Film or alternative treatment. |

5	Users are instructed to return all affected folded Sterile RENASYS [®] Transparent Film and/or the affected RENASYS [®] Gauze Dressing kits that contains the folded Sterile RENASYS [®] Transparent Film to Smith & Nephew.
6	<p>Users must complete the Acknowledgement, Receipt and Confirmation of Return Form attached with this notice and return to your local Smith & Nephew Contact as soon as reasonably practicable.</p> <p>An 'Acknowledgement, Receipt and Confirmation of Return Form' must be return even if you do not have any affected product in your inventory. If necessary, your Smith & Nephew contact can assist you in completing the form.</p>
7	Users must contact the local Smith & Nephew contact to coordinated any replacement product. Smith & Nephew will endeavor to provide replacement product.
8	Users must ensure this safety information is passed on to all those who need to be aware of it within your organization
9	Users must maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action

If you have any questions, please contact your local Smith & Nephew subsidiary on the details listed below.

<p>Contact Details of Subsidiary / Distributor:</p>

Approved by:




Smith & Nephew Advanced Wound Management Division



IMPORTANT - MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE
Acknowledgement, Receipt and Confirmation of Return Form
Response is required within 15 days

WR-2016-03

Customer Information:

Customer Name
 Street Address
 Town, State, Zip Code

RECALL: Sterile RENASYS[®] Transparent Film

I have read and understood the information contained in this letter and have distributed copies to all relevant users, as defined in the instructions.

PLEASE SELECT THE APPROPRIATE OPTION IN TABLE A

TABLE A

<p>I have checked inventory for the affected products listed in the Field Safety Notice and confirm zero inventory remaining</p> <p>[[IF YOU TICK THIS BOX PLEASE PROCEED TO THE APPROVAL SECTION]]</p>	<p align="center"><input type="checkbox"/></p>
<p>I have checked inventory for the affected products listed in the Field Safety Notice and can confirm inventory remaining</p> <p>[[IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE B]]</p>	<p align="center"><input type="checkbox"/></p>

TABLE B - ONLY COMPLETE THIS TABLE IF YOU HAVE IDENTIFIED AFFECTED PRODUCTS LISTED IN THE FIELD SAFETY NOTICE IN YOUR LOCATION AND ARE RETURNING IT TO SMITH & NEPHEW.

Part number(s)	Lot number(s)	Quantity of product returned

*ADD ADDITIONAL ROWS IF REQUIRED.

Please provide any additional information, if applicable.

IMPORTANT - MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE*Acknowledgement, Receipt and Confirmation of Return Form***RECALL: Sterile RENASYS[®] Transparent Film****APPROVAL**

Name	
Signature	
Title	
Telephone	
Email address	

PLEASE FAX OR MAIL THE COMPLETED RESPONSE FORM TO: YOUR LOCAL SMITH & NEPHEW CONTACT

ANNEX 1 - Details on affected devices

The part numbers of the affected folded Sterile RENASYS[®] Transparent Film supplied as a separate item or as part of the RENASYS[®] Gauze Dressing kits

Part Number	Product Description	Lot Numbers
66020933	RENASYS G SMALL W/SOFT PORT	2015100134, 2015100313, 2015100314, 2016040686, 2016040687
66020934	RENASYS G MEDIUM W/SOFT PORT	2015100135, 2015100315, 2015100316, 2015110540, 2016040715, 2016040963
66020935	RENASYS G LARGE W/SOFT PORT	2015100282, 2015100317, 2015110542, 2016041021
66020936	RENASYS G X-LARGE W/SOFT PORT	2016041035
66800394	RENASYS TRANSPARENT FILM KIT	2014010176, 2014011449, 2014030463, 2014040241, 2014050736, 2014051132, 2014061169, 2014113986, 2015020655, 2015040522, 2015050927, 2015060209, 2015071095, 2015101044, 2015110749, 2015120664, 2015121019
66800494	RENASYS-G MED KIT FLAT DRAIN	02014P, 05014D, 06914E, 13414K, 15414T, 16014CV, 18114AV, 23214D, 25214J, 26515H
66800495	RENASYS-G LG KIT 19FR RND DRAIN	00815K, 14014L, 23314E, 25214H, 32214D
66800496	RENASYS-G LG KIT FLAT DRAIN	00815N, 01215G, 02214J, 05014F, 09014K, 09914K, 16014F, 17514T, 24114D, 25214K, 28015M, 31714H
66800497	RENASYS-G XL KIT 19FR RND DRAIN	05014M
66800932	RENASYS HIGH OUTPUT FISTULA KT	07715M, 09214H, 15514G, 18814K, 27915G
66800933	RENASYS G SMALL w/SOFT PORT	2014010183, 2014011414, 2014020037, 2014021119, 2014021324, 2014021837, 2014030094, 2014030840, 2014030933, 2014031770, 2014040674, 2014041232, 2014041489, 2014050297, 2014050582, 2014051447, 2014051561, 2014060367, 2014060603, 2014060606, 2014071097, 2014080670, 2014080729, 2014091593, 2014091612, 2014091896, 2014091951, 2014102569, 2014103236, 2014103501, 2014103566, 2014125085, 2014125464, 2015016495, 2015016793, 2015016824, 2015020606, 2015020633, 2015021230, 2015030904, 2015030938, 2015031168, 2015050397, 2015050706, 2015051210, 2015051333, 2015060715, 2015060718, 2015060878, 2015070001, 2015070021,

66800933 (cont)	RENASYS G SMALL w/SOFT PORT (cont)	2015070057, 2015070243, 2015091343, 2015100464, 2015100652, 2015100707, 2015100859, 2015100968, 2015101007, 2015120041, 2015120046, 2015120052, 2015120061, 2015120411, 2016010750, 39907, 40151, 43250, 43251, 43252
66800934	RENASYS G MEDIUM w/SOFT PORT	2014010306, 2014010307, 2014010965, 2014011574, 2014020362, 2014020972, 2014021207, 2014021208, 2014021930, 2014021931, 2014022059, 2014022086, 2014030302, 2014030816, 2014030934, 2014031153, 2014031404, 2014031758, 2014040175, 2014041509, 2014041510, 2014042119, 2014050158, 2014050207, 2014050345, 2014050586, 201405062, 2014051041, 2014051041, 2014060684, 2014060833, 2014061007, 2014061442, 2014061669, 2014070114, 2014070520, 2014070979, 2014071068, 2014080794, 2014080836, 2014080909, 2014090181, 2014090267, 2014091758, 2014091835, 2014092091, 2014102295, 2014102318, 2014114098, 2014114125, 2014114183, 2014114284, 2014124756, 2014124797, 2014125114, 2014125177, 2014125233, 2015020672, 2015020750, 2015020781, 2015020841, 2015021100, 2015021102, 2015031154, 2015040916, 2015050291, 2015050995, 2015050996, 2015051048, 2015051382, 2015051409, 2015060395, 2015060402, 2015060912, 2015060921, 2015060979, 2015061078, 2015070313, 2015070335, 2015070348, 2015091344, 2015100024, 2015100672, 2015101328, 2015101360, 2015101522, 2015110440, 2015110767, 2015110809, 2015110931, 2015110988, 2015110989, 2015111015, 2015111261, 2015121208, 2015121237, 2016010018, 2016010772, 2016010790, 39908, 40152, 43249, 43432, 43433, 43434, 43435, 43558
66800935	RENASYS G LARGE W/SOFT PORT	2014010875, 2014010876, 2014010919, 2014010940, 2014011209, 2014011229, 2014011418, 2014020026, 2014020946, 2014021122, 2014021838, 2014021839, 2014022085, 2014030813, 2014030841, 2014031293, 2014031354, 2014031399,

66800935 (cont)	RENASYS G LARGE W/SOFT PORT (cont)	2014040860, 2014041269, 2014041410, 2014042109, 2014042113, 2014050898, 2014051040, 2014051655, 2014060089, 2014060169, 2014060274, 2014061051, 2014061333, 2014061438, 2014080369, 2014080549, 2014090036, 2014091306, 2014102445, 2014102629, 2014102650, 2014114359, 2014114527, 2014114577, 2014124708, 2014125271, 2014125307, 2014125307, 2015020993, 2015021023, 2015040809, 2015051050, 2015051077, 2015060486, 2015060493, 2015060494, 2015060507, 2015061065, 2015061135, 2015061224, 2015061265, 2015070371, 2015100539, 2015100585, 2015100603, 2015100611, 2015110023, 2015110257, 2015110291, 2015110435, 2015120445, 2015120457, 2015120752, 2015120762, 2016010895, 2016011075, 39909, 40153, 43535, 43559, 43565, 43714
66800936	RENASYS G X-LARGE W/SOFT PORT	2014010874, 2014010961, 2014040956, 2014050897, 2014080970, 2014103611, 2015021068, 2015021444, 2015040678, 2015070796, 2015100001, 2015100272, 2015101377, 2015120027
66801255	RENASYS-G 10Fr Round DRAIN KIT	01415G, 02015E, 04916J, 16914G, 2014050828, 21015G, 21015H, 32214L
66801256	RENASYS-G 10MM FLAT DRAIN KIT	05516D, 05715H, 08915E, 11214JV, 11414AV, 11414BV, 16914H, 2013050783, 2013060968, 20915T, 32115L, 32314M
66801257	RENASYS-G 15Fr Channel DRAIN KIT	08915D, 16914J, 19615V, 2014030237, 2014060209, 20815K, 20915G, 23014L, 28815K, 32215G, 32814J
66801258	RENASYS-G 19FR ROUND DRAIN KIT	05316P, 17014K, 2014030238, 20915K, 32314T